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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BURKHART, MICHAEL D

ART UNIT PAPER NUMBER

1633

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,110	Applicant(s) STEWART ET AL.	
	Examiner Michael D. Burkhart	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/14/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-83 is/are pending in the application.
- 4a) Of the above claim(s) 49-66,69-71 and 73-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67, 68, and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 11/14/2005 is acknowledged. The traversal is on the ground(s) that original claims 1-48 have been canceled and new claims 49-83 all belong to Group II. This is not found persuasive because applicant has merely re-drafted the claims to read on the same multiple inventions previously stated in the restriction requirement. The kit claims (new claims 49-59) and methods of using the kit (73-78, 81-83, and not previously presented) are considered to belong to Group III, as stated in the restriction requirement. New claims 79 and 80 are considered to be the same invention as found in Group IV, i.e. methods of detecting a disorder or disease. The new method claims 62-66 and 69-72 claim the same invention as Group I of the restriction (e.g. they are distinguished from the methods of Group II by a lack of first and second oligonucleotide "adaptor" molecules). New claims 60 and 61 are considered to also belong to Group I, although they lack the step of introducing the disclosed DNAs into a bacterial cell. New claims 67, 68 and 72 are considered to read on Group II, as they disclose the same method described in Group II of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 49-66, 69-71, and 73-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/14/2005.

Claim Objections

Claims 67 and 68 are objected to because of the following informalities:

"oligonucleotide" in lines 24 and 19, respectively, should be "oligonucleotides". Appropriate correction is required.

Claim 72 is objected to for depending from non-elected claims (claims 60, 61, 69-71).

Information Disclosure Statement

The information disclosure statement filed 9/21/04 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 67, 68, and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 67 and 68 recite, in line 2, "first and second double-stranded oligonucleotides". However, the first and second oligonucleotides are claimed as comprising "a first oligonucleotide DNA strand comprising" (line 3 of claim 67) and "a second oligonucleotide strand" (lines 8-9, claim 67). This introduces confusion as to the nature of the claimed oligonucleotides: are they double- or single-stranded? Therefore the metes and bounds of the claimed subject matter are unclear. This rejection affects dependent claim 72.

Claim 67 recites the limitations "the two arms" and "the desired insert" in line 19. There is insufficient antecedent basis for the limitations in the claim.

Claim 68 recites the limitations "the two arms" and "the desired insert" in lines 13 and 14. There is insufficient antecedent basis for the limitations in the claim.

Claim 68 recites the limitations "the vector" in line 18. There is insufficient antecedent basis for the limitations in the claim.

Claims 67 and 68 recite "the homologous sequences" in line 20 and lines 14-15, respectively, but the claims contain numerous references to "homology arms" and nucleotide sequences homologous to the homology arms or termini. It cannot be determined which of these multiple homologous sequences the term "the homologous sequence" refers to. Therefore, the metes and bounds of the claimed subject matter are unclear.

Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the vector DNA necessary to the invention is not recited in step b) of the claim, but rather "a vector" is recited in line 24. It is clear from the claims and specification that the claimed method requires the particular vector DNA described in the claims, not just "a vector".

Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the homology arms and origin of replication of the vector DNA, along with their 5' to 3' orientation; and the two termini and 3' to 5' orientation of the target DNA. These elements are disclosed as critical to the invention (see Figs. 1 to 5).

Claim 72 recites the limitation "the selectable marker" in line 4. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 72 recites the methods of claims 67 or 68 wherein the vector DNA does not contain a directly repeated sequence of five or more bases between the structural elements listed as (i)-(iii). There is no support for this limitation in the specification or claims as originally filed. Original claim 48 specified such a limitation, but only between an origin of replication and a selectable marker. Therefore, the claim contains impermissible new matter.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 67 and 68 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 53 and 54 of prior U.S. Patent No. 6,355,412 (of which this application is a CIP). This

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is a double patenting rejection. The instant claims recite the same method, using the same first and second adaptor oligonucleotides, vector DNA, target DNA, and bacterial cell expressing a bacterial recombinase as recited in claims 53 and 54 of '412. There is no difference in scope between claims 53 and 54 of '412 and the instantly claimed invention.

Conclusion

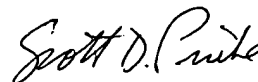
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER